REMARKS

Reconsideration of this application and reexamination of the claims in view of the amendments and remarks presented herein are respectfully requested. Claims 2, 10-12, 26, 30, 85-90, 93, 97, 106-109, and 112-115 have been cancelled, and claims 24, 27, 29, 31, 40, 83, 91, 94, 96, 98, and 103 have been amended. Claims 24, 25, 27-29, 31-34, 36, 40, 81-84, 91, 92, 94-96, 98-105, 110, and 111 are pending. Of these, claims 81-84, 104, and 105 have been withdrawn from consideration. The claim amendments find support, for example, in the claims as filed and do not add new matter.

Applicants thank the Examiner for withdrawing the restriction requirement between Groups I, II, and IV. Applicants have maintained withdrawn claims directed to Group III and renew their request that those claims be examined when the linking claims from which they depend are allowed.

Applicants also thank the Examiner for acknowledging the withdrawn and moot previous rejections at Item 2 of the Office Action.

The Pending Claims

Applicants believe the Examiner may not have understood the scope of the claims and that this may have led to confusion in the last Office Action. Therefore, before addressing the rejections directly, Applicants will explain the meaning of the claims.

Independent claim 24 recites "A method of treating a cytomegalovirus (CMV) infection of a mammal, comprising administering to the mammal a molecule that specifically binds to a DC-SIGN receptor . . . ." Independent claim 40 recites "A method

of treating a human immunodeficiency virus (HIV) infection of a human, the method comprising: administering to the human a molecule that specifically binds to a DC-SIGN receptor . . . ." Independent claim 91 recites "A method of inhibiting entry of a CMV virus into a cell of a mammal that expresses a DC-SIGN receptor, comprising administering to the mammal a molecule that specifically binds to the DC-SIGN receptor . . . ." And independent claim 103 recites "A method of inhibiting entry of an HIV virus into a cell of a human that expresses a DC-SIGN receptor, the method comprising: administering to the human a molecule that specifically binds to the DC-SIGN receptor . . . ." Thus, all of the claims recite "a molecule that specifically binds to a DC-SIGN receptor." Examples of molecules that specifically bind to the DC-SIGN receptor are specifically claimed in some of the dependent claims, such as "CMV envelope glycoprotein" (claim 27), "CMV envelope glycoprotein B" (claim 28), "a binding moiety of the CMV envelope glycoprotein B that specifically binds to the DC-SIGN receptor" (claim 29), "an antibody" (claim 32), and "mannan" (claim 84).

Without wishing to be bound to any theory of how the invention works, Applicants currently believe that when the claimed methods are practiced, and a molecule such as an antibody is administered, viral binding to DC-SIGN is blocked by the binding of the administered molecule to DC-SIGN, which then interferes with viral binding. Importantly, Applicants' claims do not recite methods that require a molecule that specifically binds to a virus or a viral protein is administered.

Claim Rejections Under 35 U.S.C. § 112

Claims 36, 102, 110, and 111 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (Office Action at Item 3.) The basis for this rejection is the Examiner's contention that "It is apparent that monoclonal antibody Mab IB10.2.6 from hybridoma cell 1B10.2.6 is required to practice the claimed invention because it is a necessary limitation for the success of the invention as stated in the claims." On this basis the Examiner concluded that: "As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public."

In response, Applicants submit a Deposit Declaration relating to the deposit of an hybridoma secreting monoclonal antibody Mab IB10.2.6 to overcome the rejection. Applicants submit that they have complied with the requirements of 37 CFR §§ 1.801-1.809 and request that this rejection be withdrawn.

Claims 2, 10-12, 24-34, 36, 40, 87-103, and 110-115 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. (Office Action at Item 4.) In support of the rejection, the Examiner stated that "[t]he claims encompass the treatment of any disease, any viral disease, CMV and HIV, wherein a competitive inhibitor (effector molecule) inhibits binding of a pathogen to a DC-SIGN receptor," and concluded that "[c]learly, Applicant[s have] not demonstrated possession of a method that treats any disease, any viral disease, CMV or HIV."

Applicants respectfully traverse the rejection and submit that the claims presented in the listing of claims herein are supported by an adequate written

description in the application as filed. Applicants note that the rejection has been rendered moot as to claims 2, 10-12, 26, 30, 87-90, 97, and 112-115 by cancellation of those claims.

In support for the assertion that Applicants have not demonstrated possession of the claimed methods, the Examiner cites *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111, for the proposition that "'applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*.'" The Examiner also cites *Fiers v. Revel*, 984 F.2d 1164, 25 U.S.P.Q.2d 1601, for the proposition that: "Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required."

In contrast to the patentee in *Fiers v. Revel*, Applicants are not claiming a compound. The pending clams all recite "a method." The claimed methods comprise administering "a molecule that specifically binds to the DC-SIGN receptor." Applicants have disclosed and specifically claimed at least three classes of molecules that can be used to practice the claimed methods, including antibodies, such as Mab 1B10.2.6, mannosylated molecules such as mannan, and CMV envelope glycoproteins, such as CMV envelope glycoprotein B. Applicants' disclosure clearly establishes that the invention can be practiced with molecules from each of these classes of compounds. In this way, Applicants have demonstrated possession of the claimed methods.

The Examiner also seemed to assert that written description was lacking for the recitation in the claims that binding to DC-SIGN is inhibited by greater than 80%. Applicants find this assertion surprising in view of the literal support for this claim

recitation at paragraph 0095 of the application as filed. In any event, Applicants have removed the recitation of "by greater than 80%" from the claims. Applicants submit that the claims as amended are supported by the specification as filed and that the skilled artisan would have concluded, based on the disclosure in the specification as filed, that Applicants were in possession of the claimed methods as of their filing date. For example, the experiments reported in Example 9 and Figure 2 show that the skilled artisan can follow Applicants' teachings to practice the claimed methods and achieve inhibition of viral binding.

Claim Rejections Under 35 U.S.C. § 102

The Office rejected claims 2, 10, 87, 88, 113, and 114 under 35 U.S.C. § 102(a) as allegedly anticipated by Littman *et al.* (WO 01/64752 A2, herein, "Littman") and under 35 U.S.C. § 102(b) as allegedly anticipated by Figdor *et al.* (EP 1046651 A1, herein, "Figdor"). (Office Action at Items 5 and 6.) Applicants have cancelled the rejected claims, rendering the rejections moot.

Claims 2, 10-12, 24-34, 36, 40, 87-103, 110-115 were rejected under 35 U.S.C. 102(b) as being anticipated by Gehrz *et al.* (WO 91/05876, herein, "Gehrz"). (Office Action at Item 7.) Applicants note that claims 2, 10-12, 26, 85-90, and 112-115 have been cancelled, rendering this rejection moot as to those claims. Applicants respectfully traverse the rejection as to the remaining claims.

According to the Office, "Gehrz discloses a method for treating human CMV with a cocktail of monoclonal antibodies, one of which binds to gp55, a subunit of envelope glycoprotein B." The Office states that "Antibodies to gp55 are binding moieties and constituents themselves." Then, apparently arguing that the antibodies of Gehrz

inherently possess the properties of the antibodies recited in some of Applicants' method claims, the Office argues that even though Gehrz "does not mention that the monoclonal antibodies bind to DC-SIGN to interrupt binding between glycoprotein B and DC-SIGN, Gehrz's antibodies are **inherently interacting with DC-SIGN**." (Emphasis added.) On the basis of this assertion, the Office stated that: "When Gehrz administers the antibody cocktail to an AIDS patient (infected with HIV), the antibody cocktail is inherently acting on DC-SIGN."

In response, Applicants emphasize that their claims recite "a molecule that specifically binds to the DC-SIGN receptor." An antibody that specifically binds to gp55 is not an antibody that specifically binds to the DC-SIGN receptor and is not a molecule that specifically binds to the DC-SIGN receptor. The Examiner seems to hypothesize that by binding to gp55, the antibodies of Gehrz inherently then act to disrupt the binding of CMV to DC-SIGN. Applicants do not know whether the Examiner's hypothesis is correct, but even if it is, that would not make the disclosure of Gehrz into an inherent anticipation of Applicants' claims. Applicants' claims do not recite binding of a protein to CMV, which then in turn has an effect on binding of CMV to DC-SIGN. Applicants' claims recite "a molecule that specifically **binds** to the DC-SIGN receptor." (Emphasis added.) Gehrz does not disclose such a molecule or a method of using such a molecule, either expressly or inherently. Thus, Gehrz does not disclose every element of the claims and does not anticipate the claims. *See* M.P.E.P. 2131.

In maintaining the rejection over Gehrz, the Examiner specifically addressed Applicants' arguments from their previous response. Applicants strenuously disagree with the Examiner's statements and will now address them in turn.

The Examiner first stated that "In response to Applicant[s'] arguments, the Office recognizes that the DC-SIGN receptor is not a CMV protein. However, the interaction between Gehrz's antibodies and DC-SIGN is expected to take place because the antibodies are effector molecules. The instant claims only require that the molecular effector be an antibody." Applicants are unsure what the Examiner means by this statement. Applicants do not agree that Gehrz anticipated any of the claims pending prior to the amendments herein. However, Applicants note that none of the amended claims recite "effector." The claims all do recite "a molecule that specifically binds to the DC-SIGN receptor." Gehrz does not disclose such a molecule.

The Examiner also stated that "the antibodies of Gehrz are expected to bind to DC-SIGN because they meet the structural requirements outlined in the claims. The functions of the antibodies are expected to be the same as those described by Applicant, lacking evidence to the contrary." Applicants are unsure which structural requirements the Examiner refers to. In any event, Applicants submit that the claims do not read on methods of using the antibodies of Gehrz and that Gehrz does not anticipate the claims.

The Examiner also stated that

> In summary, the activity of the prior art's antibody is expected to be the same as those antibodies instantly claimed. While Gehrz did not appreciate certain activities or capabilities of the antibodies, the activities and capabilities inherent in the antibodies are present regardless. In this case, the patient population is the same as Applicant's intended patient population. Therefore, administering Gebrz's antibodies, which are considered to be the same as Applicant's antibodies, would necessarily result in the binding of DC-SIGN.

Gehrz clearly teaches that the antibodies it discloses bind to gp55. One of the hallmarks of an antibody, which is necessary for its function, is that its binding is specific. Thus, because the antibodies of Gehrz recognize an antigen on gp55 the antibodies would not be expected to bind specifically to another protein, such as DC-SIGN. The Examiner has not pointed to any reason why such an antibody would bind to DC-SIGN. Absent evidence that they would, or even any plausible explanation whatsoever to imagine that they do, the antibodies of Gehrz do not anticipate Applicants' claims. Applicants submit that the claims are patentable over Gehrz because Gehrz does not disclose antibodies that expressly or inherently bind DC-SIGN.

Applicants note that some of the claims recite the word "moiety," such as claim 29, which recites "wherein the molecule that specifically binds to the DC-SIGN receptor comprises a binding moiety of the CMV envelope glycoprotein B that specifically binds to the DC-SIGN receptor." As described at paragraph 065 of the application: "A 'binding moiety' is that portion of a molecule that substantially retains the ability to bind to a second molecule when other portions of the molecule are removed or modified or when the binding moiety is placed into a heterologous context." If claim 29 is read in light of this definition, it is clear that the claim is directed to a method in which the molecule that specifically binds to the DC-SIGN receptor comprises that portion of the CMV envelope glycoprotein B that specifically binds to the DC-SIGN receptor, and that substantially retains the ability to bind to the DC-SIGN receptor when other portions of the CMV envelope glycoprotein B are removed or modified or when that portion of the CMV envelope glycoprotein B is placed into a heterologous context. The antibodies of Gehrz do not meet this definition, either expressly or inherently.

For the foregoing reasons, Applicants respectfully submit that the claims are patentable over Gehrz and request that the rejection over Gehrz be withdrawn.

Double Patenting

The Office provisionally rejected claims 2, 10-12, 87, 88, 113, and 114 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-34, 78-89, and 96-100 of copending Application No. 10/700,491. In response, Applicants note that the rejected claims have been cancelled, thus rendering this rejection moot. Applicants request that the Examiner withdraw the rejection.

Conclusion

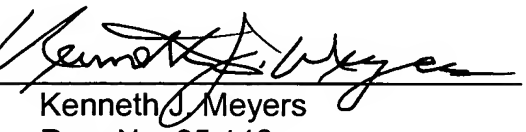
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 13, 2006

By: 

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